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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,934	05/03/2000	ANDREAS STEINMEYER	SCH1747	6707

7590 09/20/2005

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EXAMINER
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QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/509,934

Applicant(s)

STEINMEYER ET AL.

Examiner

Sabiha Qazi

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-6, 14, 19, 21-26, 28-36, 38 and 40-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-6, 14, 19, 21-26, 28-36, 38 and 40-48 is/are allowed.
- 6) ☐ Claim(s) 8-11 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

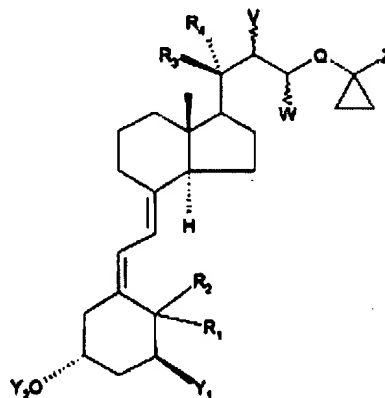
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**Non-Final Office Action**

Acknowledgement is made of the amendments filed on 5/26/05 and supplemental amendments filed on 6/15/05. Amendments are entered. Claims 1-6, 8-11, 14-18, 19, 21-26, 28-36, 38, 40-48 are pending. Claims 1-6, 14, 19, 21-26, 28-36, 38, 40-48 drawn to compounds are allowed. Claims 8-11 and 15-18 drawn to method of use are rejected. Previous rejection is withdrawn because claims are amended and arguments are found persuasive.

Instant claims are drawn to vitamin D compounds of formula (I), in claim 1, where R<sub>1</sub> and R<sub>2</sub> can be exocyclic methylene group, Z represents OH, R<sub>3</sub> can be CH<sub>3</sub>, R<sub>4</sub> can H, V is OH and W is H or together may form a double bond, and Q is straight or branched hydrocarbon which can be substituted by OH at any position.



(I) of present invention.

**The nature of the invention****Claim Rejections - 35 USC § 112 (1<sup>st</sup> Paragraph)**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 8-11 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the certain type of cancer, does not reasonable provide enablement for the treatment of tumor diseases, AIDS, Alzhiemer or degenerative diseases. Examiner will explain taking the example of tumor/cance.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988).

Among these factors are;; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6); (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation. The instant disclosure fails to meet the enablement requirement for the following reasons:

(1) the nature of the invention

Claims 8-11 and 15-18 are drawn to method of treating

- Alzheimer's disease,
- AIDS,
- Tumor diseases,
- Precancerous stages,
- Disorders of immune diseases,

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- Auto-immune disease
- Degenerative diseases of peripheral and central nervous system and many more.

**The predictability or unpredictability of the art**

Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds, *In re Buting*, 163 USPQ 689. The disclosure provides no indication of whether the compounds treat all cancers. To make clearer the lack of enablement for treatment of all cancer, extrinsic evidence is supplied by Draetta (Ann. Reports Med. Chem.), Draetta et al. in "Annual Reports in Medicinal Chemistry", 1996, Academic Press, San Diego, pp 241-246, final sentence on page 246 although many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely." Since no universal cure for cancer has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat all cancers. Thus, those assays are not sufficient to enable such claims.

Further, in the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. Different agents are used for different forms of cancer and no single agent is listed as a treatment of every single type of cancer. Balasubramanian reference (Recent Developments in Cancer Cytotoxics) on page 151 first paragraph **"the successful treatment of solid tumors remains a formidable challenge."**

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**The breadth of the claims**

Claims are broad as treatment of various disease such as AIDS, Alzheimer, and degenerative diseases are claimed, any evidence for the treatment has not been shown.

**The amount of direction or guidance presented**

Applicant has provided no evidence, which incontrovertibly demonstrates that the tests set forth in the instant specification are art-recognized, reliable predictors of successful treatable, in vivo, of all cancers/tumors or AIDS or Alzheimer and other diseases.

**The quantity of experimentation necessary**

Since claims are broad and there is no evidence provided by Applicants to treat tumors, AIDS, Alzheimer and other diseases as claimed, the worker of ordinary skill in the art would not be able to practice the instantly claimed method, since no description is found of an actual method wherein a cancer/tumor, AIDS, Alzheimer, degeneration in a host is treated. On page 27 the listed provides cell-differentiating activity of certain compounds in DR HL 60.

Applicants fail to fulfill the requirement of 35 U.S.C. 112, first paragraph, by failing to provide an adequate written description of how to treat all tumors and other diseases in a single host.

Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

**Communication**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saturday, September 03, 2005

  
SABIHA QAZI, PH.D  
PRIMARY EXAMINER